



HEALTH CARE INDUSTRY MARKET UPDATE

Medical
Devices
& Supplies

December 5, 2003

Dear Friends of CMS:

For the last two years CMS has studied and reported the financial position of health care companies with the goal of educating policy makers. Because many of these providers derive a large portion of their revenue from the Medicare, Medicaid, and SCHIP programs, they are essentially government contractors and should expect to receive profit margins that are stable, predictable, and *boring*. In the past, certain health care industry sectors have experienced rapid government payment rate (and profit margin) increases or have been influenced by incentives that encouraged inappropriate utilization. These sectors often suffered financially when corrective policy action was taken, putting beneficiary access to care at risk.

As the regulators of nearly \$600 billion per year of Medicare, Medicaid, and SCHIP funds, it is incumbent upon us to better understand the finances of our contractors, health providers, and other related businesses that provide services to the more than 70 million beneficiaries these programs serve. I believe that by having an accurate understanding of provider financial status, policy makers will be better able to understand the impact that changes to payment, coverage, and policy will have to CMS beneficiaries and their providers.

Through the *Health Care Industry Market Update*, a regular series of reports on the major health care industry sectors, we have been able to help educate policy makers in CMS, HHS, and the Congress regarding the financial position of these companies and the impact that changes to laws and regulations have on providers' ability to serve patients. If health plans or providers are struggling to serve our beneficiaries, we should have a thorough understanding of their real financial status to assess the true level of need. Many investment banking firms conduct detailed analyses of major health providers, both for the equity investors in for-profit companies, and for the debt holders of for-profit and not-for-profit entities. Health systems typically provide these investors with clear financial data. These data can be used by regulators and legislators to assess funding adequacy or the need for regulatory reforms. CMS' Office of Research, Development & Information (ORDI) has gathered research reports from the major investment firms, summarized their analyses, and condensed them into a short, and hopefully, understandable format. The primary people at CMS assigned to this task are Lambert van der Walde and Laurel Lindstrom.

This Market Update focuses on medical device and supply manufacturers, updating our first report published October 10, 2002. CMS will continue to review the major provider and supplier sectors. I believe this effort has added to the understanding of CMS programs and the financial position of health care companies. Comments on the content and format of this report are welcome. I want to make this as consumer friendly as possible for everyone who reads it. Please provide comments to Lambert van der Walde at Lvanderwalde@cms.hhs.gov or Laurel Lindstrom at Llindstrom@cms.hhs.gov.

Sincerely,

Tom Scully

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Wall Street's View of Medical Device and Supply Manufacturers

Large medical device and supply companies continue to show strong financial performance.

- ◆ **Analysts believe that industry fundamentals are strong and expect continued revenue growth through the introduction of new technologies.**
- ◆ **Large device and supply companies have healthy access to capital, but can often fund their businesses with cash generated from operations.**
- ◆ **Many of the industry's small companies are having difficulty securing venture capital financing to fund operations.**
- ◆ **Merger and acquisition momentum is expected to increase as larger manufacturers seek to fill their product pipelines with technologies developed by early-stage innovators.**

CONTENTS

Executive Summary	3
Wall Street's View	4
Industry Overview	6
Industry Performance	9
Revenue Growth	9
Revenue Sources	10
Medicare Coverage	10
Medicare Payment	11
Expense Trends	15
Net Income	16
Access to Capital	18
Large Device and Supply Companies	18
Small Device and Supply Companies	21
Merger and Acquisition Activity	23
Summary	24

EXECUTIVE SUMMARY

Introduction of new technology devices has driven sales growth over the last year.

Wall Street analysts generally believe that current valuations of companies in the \$75 billion medical device and supply industry reflect continued strong top-line performance and sound underlying financial fundamentals. Over the last year, certain sub-sectors of the medical device industry have driven industry-wide revenue growth due to the introduction of several new technologies, such as drug-eluting stents and cardiac rhythm management devices. Similar growth is anticipated through the introduction of new products within the spinal and heart valve repair sectors.

Investors are most attracted to companies developing new technologies and methods. This investor interest drives companies to continually produce innovative products or to seek these through a business acquisition. Although merger and acquisition activity within the industry slowed in recent years as companies focused on internal operations, analysts expect manufacturers may become increasingly acquisitive as they seek to fill thin product pipelines.

The speed of technology adoption often depends on a combination of clinical benefit data, regulatory decisions, and manufacturer production and distribution. Historically, analysts noted that the medical device industry benefited from acceleration in Food & Drug Administration approval timelines. Medicare coverage and provider payment decisions are also considered critical to technology adoption, resulting in substantial investor scrutiny over these regulatory decisions.

Large medical device and supply manufacturers enjoy strong profit margins.

While small, developing medical device companies significantly contribute to industry innovation, they also incur losses while developing their first product. In contrast, major medical supply manufacturers have highly diversified product portfolios (often including a mix of devices, pharmaceuticals, hospital supplies, and consumer goods) and generate stable profits. While the gross margins of both hospital supply and medical device manufacturers have remained consistent (around 52% and 71%, respectively, over the last several years) supply company margins have experienced a slight decline due to negative investor sentiment towards their pharmaceutical operations. Research and development spending is used by analysts as an indicator of a company's commitment to long-term success. R&D spending for most medical device companies averages 9%-10% of revenues and remains in line with historical trends. Median net income margins for the medical device manufacturers improved substantially from 2001 through the third quarter of 2003 to 18% (from a low of 11% in 3Q2001). Supply companies have experienced less volatility in historical net income margins, achieving a 13% margin through 3Q2003.

Because of their continued strong fundamentals and expected continued revenue growth, the large medical device and supply companies enjoy strong access to capital through both the public debt and equity markets. Medical device manufacturers, in particular, have rewarded investors with consistent stock market growth.

Access to capital continues to be limited for small medical device companies.

Small medical device companies continue to experience limited access to capital. Venture capital investors, the main source of capital for these emerging companies, have become more conservative in their evaluative processes and in their capital contributions due to the protracted investment periods and limited liquidity options. Venture capitalists are seeing preliminary signs of increased investor fund flows.

WALL STREET'S VIEW

Valuations are strong among medical device manufacturers.

Analysts believe medical device and supply manufacturers are strong, but that they may be reaching full valuations. Glenn Reicin of Morgan Stanley notes “fundamentals still look very strong [in the hospital supplies and medical technology industry]...and growth looks relatively robust compared with the pharmaceutical industry and projected S&P 500 earnings. That said, we think that this may already be reflected in the valuation of many of the stocks in our coverage universe.”

Growth within the medical device and supply manufacturing industry is largely product driven. As a result, analysts focus on companies best poised to capitalize on emerging technologies.

New cardiovascular and orthopedic devices drove industry performance in 2002.

Recent sales growth in the medical device sector resulted from the introduction of new technologies, specifically within the cardiology and orthopedic sectors. In the cardiology sector, drug-eluting stents and cardiac rhythm management devices have been the major focus for investors. Daniel Lemaître of Merrill Lynch notes, “the \$3.7B high-powered [cardiac rhythm management] market is one of the fastest growing segments in the Med Tech industry. Solid 20% type growth is expected over the next few years as penetration increases into the vastly under served patient population.” David Lothson of UBS stated recently that “this year has also been the year of the drug-eluting stent (DES) for investors.” He notes that new investors to the sector may not see a return because of valuations that may already reflect expected market growth, and mitigating factors such as large size of company and late market entry. Nevertheless, the American DES market is expected to experience continued growth. Michael Weinstein of JP Morgan believes the US market for DES may reach \$3.35 billion in 2005, which represents a tripling of the market since 2002. Growth thereafter is expected to slow to 5-6% as pricing declines and DES penetration reaches 80% of the total stent market.

Orthopedics companies are experiencing continuing sales growth.

The orthopedics sector is also viewed positively by analysts due to an aging population and more aggressive use of joint replacement by surgeons in younger patients. Jason Wittes of Morgan Stanley believes that sales in the total joints industry¹ will grow at rates in the low to mid-teens for the next several years. Company growth in the total joints industry is driven by pricing power, increasing procedure rates, and product mix. Wittes states “given the strong customer loyalty and virtual oligopoly that exists in the market today, we see little reason to believe that this strong pricing environment will change near term.” Further, Wittes states that the number of procedures will continue to rise as the pressure to maintain an active lifestyle becomes more pronounced and younger patients receive joint replacements (and must undergo revision surgery 10-15 years later when the joint wears out). Analysts note that within the medical device sector, strong relationships exist between the physician and the industry sales reps, which creates barriers for new companies to gain market share. Further, physicians are notoriously price insensitive when making device selections. The combination of these factors allows manufacturers to dictate pricing and is expected to support a continued strong pricing environment.

¹ Total joints industry consists of manufacturers of mechanical replacements for hips, knees, and extremities.

Over the last year, hospital supply companies have not seen revenues grow at the same rate as for the medical device manufacturers. As Glenn Reicin of Morgan Stanley notes, "Unfortunately, given the reliance on pharmaceuticals for some of the companies in this universe, performance was held back by the overall performance of the [pharmaceutical sector]."

Investors closely monitor emerging technologies.

Just as DES and cardiac rhythm management (CRM) technologies altered the medical device industry landscape, analysts believe new technologies such as percutaneous (or, "through the skin") heart valve repair and replacement and "non-fusion" technologies in the spine market will have similar, far-reaching impact. As David Lothson of UBS explains, "Among the most successful ways to invest in the medical device industry has been spotting markets that transition from highly invasive surgeon-dominated procedures to less invasive ones in which non-surgeons (interventionalists) can perform." He cites the example of the shift from cardiac bypass surgery to angioplasty. In the case of percutaneous heart valve repair, the procedure would be performed through a catheter inserted in the leg, as opposed to open heart surgery. The patient's ability to retain mobility through non-fusion technologies illustrates its clear utility in the \$3.2 billion United States spinal repair market. Referring to conventional surgical techniques, Michael Weinstein of JP Morgan notes "even with the advent of [bone regrowth materials] and minimal access technologies, fusion still remains mostly a carpenter's or stonemason's trade...and the procedure itself remains fundamentally unchanged."

Impact of public payor decisions is mitigated by private payor reimbursement.

Private payors drive pricing cycles in the medical devices industry. Orthopedics analyst Jason Wittes of Morgan Stanley states "while [Medicare] DRG codes are relevant...private payers are a more important component in [the] price equation because reimbursement rates are significantly higher through private payers...These higher rates help keep the orthopedic department a profit center for the hospital." Daniel Lemaitre of Merrill Lynch comments on the Medicare inpatient prospective payment system update for FY2004: "While the prices [manufacturers] charge for CRT-Ds are independent of [Medicare] payment levels, the higher hospital reimbursement levels could lead to increased utilization." Lemaitre nevertheless continues, "the increases in cardiology [Medicare payment] and the new [Medicare code] for CRT therapy bodes well for the \$7.7B CRM market."

Acquisitions, which historically centered on promising new technologies, have slowed in recent years. Merger and acquisition activity has slowed in the broader medical devices and supply industry. David Lothson of UBS notes that consolidation over the last six years within orthopedics has led to the rise of oligopolies. As a result, "three companies now each have roughly 1/4 of the global reconstructive orthopedic market; each achieved their positions through acquisitions since late 1998." Large medical device and supply companies are now finding the need to fill thin product pipelines or create growth to follow recently introduced technologies and are expected to accelerate the acquisition of smaller companies.

Consumer consumption within the medical device and supply industry totaled \$75 billion in 2002.

INDUSTRY OVERVIEW

The U.S. medical device and supply market generated approximately \$75 billion in sales in 2002. Medical devices and supplies are used in life-saving and life-enhancing medical procedures and include products such as pacemakers, coronary stents, hip implants, catheters, wound dressings, surgical instruments, gauze, and implantable defibrillators.² Wall Street analysts and investors typically split the industry into two major sectors: medical device companies, which manufacture devices such as pacemakers or orthopedic implants, and medical supply companies, which manufacture hospital supplies such as syringes or wound dressings. The industry continually evolves as technology improves to serve broader patient populations, reduce complications, and improve medical outcomes.

Investors generally believe that medical device companies enjoy higher revenue and earnings growth compared to their supply counterparts. For example, implantable devices that are sold to medical specialists such as interventional cardiologists and orthopedic surgeons are more profitable than commodity products such as tongue depressors or gauze manufactured by medical supply companies. As such, device manufacturers can derive greater value in the market, although at the expense of greater risk in product development.

The supply business tends to have a more stable and predictable financial performance, which can be particularly attractive in volatile markets. The distinction, however, becomes less defined with major medical supply companies, such as Johnson & Johnson and Abbott Laboratories, which derive a large portion of revenues from medical devices, pharmaceuticals, and consumer goods in addition to medical supplies. Figure 1 below shows the largest companies that comprise the medical device and supply industry.

Figure 1: Largest Medical Device and Supply Companies

(\$ in millions)

	Ticker	Market Cap		Ticker	Market Cap
Medical Device Companies			Medical Supply Companies		
Cardiology					
Medtronic Inc.	MDT	\$ 56,382	Johnson & Johnson	JNJ	\$ 145,914
Boston Scientific Corp.	BSX	29,753	Abbott Laboratories	ABT	70,789
Guidant Corp.	GDT	17,665	Baxter International Inc.	BAX	17,235
St. Jude Medical Inc.	STJ	10,673	Becton Dickinson & Co.	BDX	10,282
Edwards Lifesciences Corp.	EW	1,814	C.R. Bard Inc.	BCR	4,017
Orthopedics					
Stryker Corp.	SYK	\$ 16,356			
Zimmer Holdings Inc.	ZMH	16,323			
Biomet Inc.	BMET	9,242			
Smith & Nephew PLC	SNN	7,469			

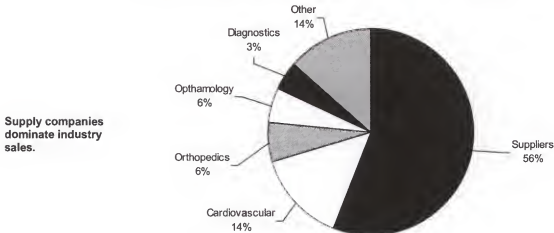
Source: Bloomberg, as of December 3, 2003.

Notes: Wall Street medical technology analysts typically categorize Johnson & Johnson and Abbott Laboratories as medical supply companies despite their diversified revenue bases, particularly in pharmaceuticals.

² Durable medical equipment (DME) such as wheelchairs and walkers are not covered in this report.

The U.S. medical device and supply industry can be divided into six major sectors. The Merrill Lynch Medical Technology & Hospital Supply Composite Index, which consists of 109 companies, serves as a useful proxy for the medical device and supply industry. Industry sector division is illustrated in Figure 2 below.

Figure 2: Top Six Sectors of the Medical Device and Supply Industry by Sales, 2002



Source: FactSet, Merrill Lynch

Note: Composite index of 109 companies in the Merrill Lynch Medical Technology & Hospital supply Composite Index.

Medical supply companies, including Johnson & Johnson, Abbott Laboratories, Baxter International, Becton Dickinson, and C.R. Bard, account for about 56% of the industry's sales. The cardiovascular device companies, which manufacture items such as stents, pacemakers, and defibrillators, follow at a distant second place with approximately 14% of the revenues of the industry. The major companies in this sector, include Medtronic, Guidant, Boston Scientific, St. Jude Medical, and Edwards Lifesciences, and comprise the majority of this sub-sector's revenue. Orthopedic-focused manufacturers, including those making hip and knee replacements and orthobiologics that stimulate bone growth, have 6% of the total industry revenues. The remainder of the industry includes ophthalmology devices, instruments, diagnostic equipment, blood products, respiratory/patient monitoring equipment, imaging devices, lasers, surgical instruments, ObGyn/urology products, and other implantable devices.

The largest 2% of the 6,000 U.S. medical device firms log nearly half of the industry's sales. Company sizes vary greatly, ranging from small companies consisting of a single inventor to Johnson & Johnson's staff of over 100,000 employees. The Lewin Group estimates that 80% of these medical device companies are small and emerging firms.

Small companies have historically made a critical contribution to medical device innovation. Despite their size, small companies disproportionately contribute to the development of innovative technologies. The Lewin Group estimates that small companies (those with revenues of less than \$100 million) generate 28% of R&D spending by the industry, but contribute only 10% of total sales. In order to bring their products to market, small companies often collaborate or combine with larger companies

to leverage resources including stable funding, manufacturing capabilities, and marketing distribution channels. In addition, larger companies may have more experience conducting clinical trials, and managing complex regulatory and payment issues. Morgan Stanley's Reicin describes this relationship: "Smaller companies in the sector are likely to play important roles in feeding the larger companies with smaller-scale innovative technologies. In turn, these companies will rely on larger companies as distribution partners and investors." Some smaller companies operate independently, but are challenged to fund research and development, manufacturing, and distribution.

Key drivers for product development include clinical benefit, technological advancement, and first-mover advantages. A new medical device can generate demand and command a premium price if it is believed to reduce medical complications and lead to better medical outcomes. Technology with positive clinical outcomes opens new markets and has the ability to significantly change a company's market share in this highly competitive industry.

Relatively short product life cycles for medical devices amplify the need for strong management skill and execution strategy. For a new product to succeed in the market, a medical device company's management team must execute an effective manufacturing and distribution strategy. Product life cycles are relatively short because medical device manufacturers and their competitors continually develop smaller, faster, and cheaper versions of existing devices. In addition, patent protection of a new technology can often be challenged or circumvented and lacks the same level of protection as a pharmaceutical company's "composition of matter" patent on the specific molecule.

Regulatory hurdles provide high barriers to entry and drive competition within the industry. The private sector funds the majority of research and development costs, and relies on strong intellectual property rights to protect this investment in research. Any new device requires clinical studies to show the device is safe and effective, which are then submitted to the Food & Drug Administration (FDA) for review. If the device obtains FDA approval, the company typically seeks Medicare coverage and payment from CMS. The manufacturer may seek favorable distribution terms with a group purchasing organization (GPO) contract, which offers volume discounts to member hospitals. The speed of technology adoption often depends on a combination of clinical benefit data, regulatory decisions (including approval, coverage, and payment), and distribution.³ Daniel Lemaire of Merrill Lynch notes "An arduous FDA review process provides medical technology investors with the ability to 'see the future' since devices are often launched in Europe, months, and sometimes years, ahead of the U.S. approval."

³ For a review of the FDA approval process, refer to CMS Health Care Industry Market Update: Medical Devices & Supplies, October 10, 2002. A summary of Medicare coverage and payment policies begins on page 10 of this update.

INDUSTRY PERFORMANCE

Profitability within the device and supply industry varies. Many small, emerging medical device companies incur losses while developing their first product. Established medical device manufacturers have highly diversified product portfolios and generate more stable profits. This analysis focuses on the financial performance of the largest medical device and supply companies that are most widely followed by Wall Street analysts.

Revenue growth driven by technological improvements

Over the last decade, the average annual revenue growth of the medical device and supply industry averaged 15%, or 23% for medical devices and 7% for medical supply companies. Revenue growth for device makers through most of the 1990s accelerated due to new product launches, while supply companies' growth was gradual. (Companies that Wall Street classifies as medical supply companies often have large, diversified revenue bases that include supplies, devices, pharmaceuticals, and consumer goods.) Device maker revenue growth began to slow, dropping from 20% average annual growth in 1999 to 5% in 2000, due to slowed growth of key market segments including bare metal stents and implantable cardioverter defibrillators (ICD).

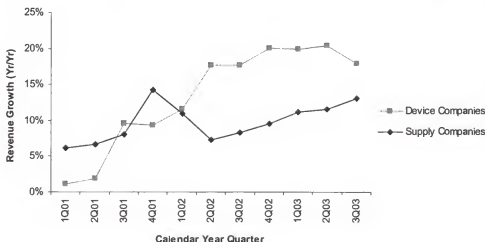
In the 2002 CMS report on Medical Devices, it was noted that revenue growth would accelerate due to the introduction of several new technologies, including drug-eluting stents (DES) and ICDs that combine cardiac resynchronization therapy (CRT-D) for congestive heart failure. Dave Lothson of UBS notes that the medical device industry, and CRM manufacturers in particular, generally do not compete by discounting prices. Rather, they focus on product differentiation through sales and marketing efforts. Therefore, increasing prices and volumes drive rapid revenue growth. With the introduction of CRT technology, manufacturer growth rates doubled through 2002-2003. In the meantime, Lothson notes "the move to drug-eluting stents from the bare metal devices currently in use is essentially a huge mix shift, revaluing the market upward by several billion dollars," which further contributes to the revenue growth seen over the last year. Going forward, as growth from CRT and DES flattens, new technologies such as percutaneous heart valve repair and replacement may drive continued growth.

Supply companies produce consistent growth.

New technologies introduced in 2002 contributed to significant growth within the medical device industry.

Figure 3: Median Revenue Growth Rate Quarterly Trends, 2001 to present

Both medical device and supply companies have experienced consistent revenue growth.



Source: Company filings.

Notes: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Revenue Sources

Medical device companies sell products directly to providers (e.g., hospitals and skilled nursing facilities), while third-party payors (e.g., private insurance, Medicare, and Medicaid) typically pay providers a bundled rate. This bundled rate covers the various costs of the procedure, including the devices and supplies used. The Medicare coverage and payment process for prospective payment systems is explained below.

Medicare Coverage of Medical Devices

In order for Medicare to pay for a provider's use of a device, it must be covered. To obtain Medicare coverage, a medical device must first fit into a benefit category that is defined by federal statute. For example, preventive services and tests generally are not covered under Medicare, although many services have been specifically provided for by Congressional action. (For example, Medicare currently covers mammography, prostate cancer screening, and influenza vaccinations.) The second criterion is that the item or service must be reasonable and necessary to treat the patient's medical condition.

Local Coverage Determinations

The majority of coverage decisions are made at the local level by Medicare contractors: the "fiscal intermediaries" that process claims from facilities and the "carriers" that process claims from physicians and labs. To allow for regional differences in medical practice, Medicare provides contractors some flexibility in making coverage decisions. Labeled indications for new, FDA approved devices are paid without specific review by contractors. Coverage for a specific device may be determined on a case-by-case basis if the device is brought to the contractor's attention or if the contractor becomes aware of it when reviewing trends in previously paid claims. If there is an unusually high volume of high-cost claims or denials for a specific medical device (or drug or service), the contractor may issue a local medical review policy (LMRP). During the LMRP development process, a contractor gathers and examines the clinical evidence and determines whether the item or service: 1) has a benefit category, 2) is not statutorily excluded, and 3) is reasonable and necessary.

Most Medicare coverage decisions are made at the local level by Medicare contractors.

The contractor usually posts the draft LMRP for 45 days of public comment, reviews these comments and any new data, and finally, posts the final LMRP. During the development of most LMRPs, carriers are required to consult with the Carrier Advisory Committee (CAC), a panel of local physicians. Fiscal intermediaries generally develop their LMRPs with input from medical providers and organizations. In addition, all contractors ask for public comment and hold open meetings to discuss their draft LMRPs. Effective October 1, 2002, each contractor must develop an LMRP reconsideration process to allow beneficiaries and providers to submit suggested revisions to LMRPs along with clinical evidence that supports the change.

National Coverage Determinations

A National Coverage Determination (NCD), which supercedes local policies, is triggered by either the request of an outside party (often the manufacturer) or by CMS. In the absence of an external request, CMS generally initiates an NCD when the item or service raises significant scientific issues, could have a substantial impact on the Medicare population, or there are major variations in local policies. CMS conducts a complete evidence-based review to determine if the item or service improves health outcomes and therefore, is reasonable and necessary. CMS must also make a benefit category determination; that is, ensure that the item or service is included within the array of Medicare benefits set forth by statute. At the beginning of each NCD, CMS posts a tracking sheet and allows for 30 days of comment to be reviewed during the decision process. Each NCD includes a complete technology assessment process, including collection and careful evaluation of all relevant data. For some NCD assessments, CMS requests external assistance and/or the independent review of the Medicare Coverage Advisory Committee (MCAC). Once a policy decision is made, a Decision Memorandum is posted to summarize the analysis and inform the public of intended implementation. Implementation of the new policy may take up to 270 days between the issuance of an NCD and the deadline by which individual Medicare contractors must reflect the coverage decision in their processing systems.

National Coverage Determinations (NCDs) are triggered by the manufacturer or by CMS when a universal policy is necessary.

Medicare Payment of Medical Devices and Supplies

Medicare does not make direct payments to manufacturers for any medical devices or supplies (except for some DME and home health products). Instead, it pays bundled rates to hospitals and other providers for care provided to beneficiaries under its various prospective payment systems (PPSs). Thus, the price that a device manufacturer charges a hospital will likely be different from the bundled payment the provider receives for the total case.

Prospective Payment Systems

A PPS encourages providers to operate efficiently by paying the same base amount to all providers for similar cases. The base rate in each PPS is adjusted for several factors. Some factors are common across PPSs (e.g., geographic differences in costs) while others are unique to an individual PPS (e.g., an adjustment for graduate physician medical education in the hospital inpatient PPS). Provider costs vary from case to case. The bundled payment rate is based upon the average resources required to treat a specific category of clinically similar patients relative to the resources required to treat patients in other categories. In some payment systems, the relative cost is compared to the average cost for all patients in that payment system (e.g., inpatient PPS) while in others the relative cost is compared to the average cost for patients in one "benchmark" category (e.g., outpatient PPS). In both cases, it is expected that the gains providers incur for low-cost cases will

Medicare bundled rates are reweighted annually.

offset losses for high-cost cases, assuming sufficient patient volume and mix. The resources required to complete treatment may include labor, facilities, malpractice insurance, pharmaceuticals, medical devices, and medical supplies. Expected resource utilization can vary because of the diagnosis, procedure(s) to be performed, or the relative acuity of each patient.

PPS Updates

As noted above, Medicare calculates the payments for each case based on the relative weight of resource utilization for the category in which the case is assigned compared to other cases. These relative weights are multiplied by a dollar amount (known as the standardized amount in the inpatient PPS and the conversion factor in the outpatient PPS) to calculate the actual payment for each case. These amounts are further adjusted for various factors that vary across payment systems.

Medicare PPSs are designed to be flexible over time—each payment classification is reweighted annually based on the most recently available claims information submitted by providers. CMS analyzes claims information annually to account for changes in resource utilization. Changes in resource utilization may be due to a number of factors, including changes in the relative cost of providing services, changes in medical practice or technological improvements that result in price changes.

New devices that represent incremental or marginal changes to existing technology and whose cost is similar to existing technology are typically covered by Medicare contractors as described above. Incremental increases in Medicare payment for procedures using new devices that are significantly more expensive than existing devices may trail behind the date upon which the new device is introduced due to the time delay in the payment system update cycle. (These expensive new devices may represent either incremental or substantial innovation.) Additional provider expenses related to expensive new devices are sometimes offset by supplemental new technology payments, which are discussed below. Any delay in the upward adjustment of payment to providers on the front end for more expensive technologies is often made up by a delay in the reduction to payment on the back end. This occurs as the acquisition costs to hospitals for these specific devices declines over time in relation to Medicare payment. This acquisition cost decline is attributable to market forces such as competition from other manufacturers or provider adoption of even more advanced, next-generation technologies. It is important to note that Medicare will almost always begin making some sort of payment once the technology is approved.

Figure 4 presents the requirements of the traditional Medicare coverage and payment process for the inclusion of new technology.

Figure 4: Medicare New Technology Coverage and Payment Process Requirements

In order to be covered and paid by Medicare, these five requirements must be met. The process for each may overlap and may vary in order.

-
- FDA approval/clearance:
 - Device must be deemed safe and effective.
 - Medicare benefit category decision:
 - Device must fit into a benefit category defined by federal statute.
 - Coverage:
 - Device must be medically reasonable and necessary for treatment.
 - Coding, the device may be placed into a(n):
 - Existing code
 - A temporary "catch-all" code
 - A new code
 - Payment adjustments are made to:
 - Inpatient PPS
 - Outpatient PPS
 - Other fee schedule
-

Source: CMS, Center for Medicare Management

While the bundled payment amounts may not always fully reflect new technology cost, new devices and procedures can be reflected in and adjustments made to these bundled payments in as little as twelve months for the inpatient PPS and as little as four months in the outpatient PPS. There have been recent cases in which CMS has accelerated certain new technologies (such as drug-eluting stents) through this process in order to ensure faster beneficiary access to new technology.

Medicare Supplemental New Technology Payments

Historical claims data typically do not exist for a new device. Under the inpatient and outpatient PPSs, Congress has directed CMS to calculate supplemental new technology payments to increase beneficiary access to new, more expensive technologies. Over time, Medicare uses actual hospital claims data to adjust payments of bundled rates, ending the use of supplemental payment for the device. This system can cause wide fluctuations in payment rates, especially during the early years of a new technology.

New Technology Special Add-on Payment in Hospital Inpatient PPS

In the Benefits Improvement and Protection Act (BIPA) of 2000, Congress instructed CMS to create procedures and criteria for making new technology payments within the inpatient prospective payment system (IPPS). These payments are capped at 1% of total IPPS spending. CMS set three new technology payment criteria for the new technology add-on payment, all of which must be met. The new technology must be:

- 1) new,
- 2) a substantial medical improvement relative to existing technology, and
- 3) of sufficient cost.

Medicare makes special add on payments for new technology based upon manufacturer-supplied prices.

To be eligible to receive any new technology add-on payment, the expected average charge for cases using the new technology must be greater than one standard deviation above the standardized average charge for all other cases in the diagnosis related group (DRG) to which the cases using the new technology would be assigned. Beginning in FY2005 (for which applications have already been received), this threshold will be lowered to 75% of one standard deviation. CMS compares total charges for cases using new technology to other cases in the same DRG because a new technology can affect other costs of the procedure (e.g., increased use of other supplies, decreased length of stay, etc.). If the new technology meets the three requirements above, for each case using the new technology CMS will pay the sum of: (a) the DRG payment for the DRG into which the case is assigned and (b) half of the difference between the DRG payment and the cost of the particular case using the new technology. If the actual costs of the new technology case exceed the DRG payment by more than the cost of the new technology, Medicare payment would be limited to the DRG payment plus 50% of the new technology. An example of this calculation can be found on page 18 of the October 10, 2002 CMS Health Care Industry Market Update Medical Devices & Supplies.

New Technology Transitional Pass-through Payments in Hospital Outpatient PPS

CMS uses hospital claims data to determine the relative weights and payment rates for ambulatory payment classification (APC) codes in the outpatient prospective payment system (OPPS). Certain new technology items, such as drugs, biologicals, and devices for which costs are not adequately represented in this claims data receive transitional pass-through payments in addition to the payment for the APC with which the new technology is associated. Pass-through payments are based on a hospital's cost⁴ for the device less any amount that is already incorporated into the APC procedure for device-related costs. In order to be considered for a pass-through payment, a device must be considered to have a cost that is "not insignificant" in relation to the APC payment for the procedures or services associated with the device.⁵ Pass-through payments are made for at least two years but not more than three years, after which the hospital claims data for those new devices are folded into the applicable APC payment.

For 2004 and subsequent years, CMS has the authority to set the pass-through at up to 2.0% of the projected total OPPS payments. If CMS estimates before the beginning of a calendar year that the total pass-through payments will exceed the limit for that year, CMS is required to impose a pro-rata reduction across all transitional pass-through payments to ensure that the limit is not exceeded.

Pass-through payments for new technologies are in addition to APC payments.

⁴ A hospital's cost for a device is calculated by adjusting the hospital's reported charge for the device using the hospital's own cost-to-charge ratio.

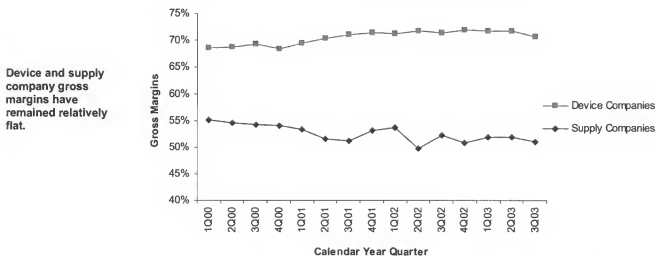
⁵ To meet the "not insignificant" cost threshold: (a) the average cost of the new device must exceed 25% of the OPPS payment for that APC, (b) the average cost of the new device must exceed the cost of the device-related portion of that APC by at least 25%, and (c) the difference between the average cost of the new device and the cost of the device-related portion of that APC must exceed 10% of the total APC payment.

Expense Trends

Costs of Goods Sold

Costs of good sold (COGS) is a manufacturer's cost of buying raw materials and producing finished goods. The gross margin is the percent of total revenues remaining after deducting COGS. According to Daniel Lemaitre of Merrill Lynch, the industry has improved gross margins over time due to productivity gains and product mix shifts, successfully offsetting pricing pressure. Over the past three years, gross margins have appeared relatively constant for medical device manufacturers (71% in 2002) and have been declining slightly for supply companies (52% in 2002). This is seen on a quarterly basis in Figure 5.

Figure 5: Median Gross Margin Quarterly Trends, 2000 to present

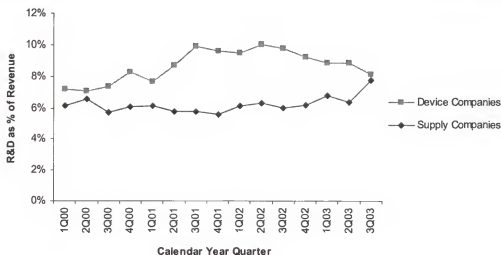


Research and Development

Research and development (R&D) is perhaps the single most important expense of a medical device company. The competitive nature of the industry, characterized by the rapid pace of innovation and short product life cycles, demands a huge commitment to R&D. One useful measure of R&D across companies of different sizes is the amount of R&D spending relative to the amount of the company's total revenues. Within the large medical device manufacturer universe, the average company's research and development costs approximate 9%-10% of sales, as seen in Figure 6. According to Merrill Lynch, medical device R&D spending is lower than that of the pharmaceutical industry because clinical trials tend to be smaller (usually only a few hundred patients) and are therefore less costly. Notably, smaller innovative companies often spend a very large portion of their revenue on R&D.

Analysts also scrutinize R&D spending as a sign of ongoing, sustained commitment to ensure a company's long-term success. Morgan Stanley's Reicin considers R&D spending to be "an important indicator of success." Companies such as Medtronic and Guidant, which are focused on higher technology devices, have a greater R&D expense than companies focused on lower-tech (and thus lower-risk) devices.

Figure 6: Median R&D, as a Percent of Revenue, Quarterly Trends, 2000 to present



Source: Company filings.

Notes: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Selling, General, and Administrative

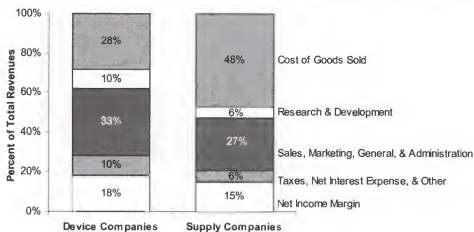
The medical device industry spent an average 34% of revenue on selling, general, and administrative (SG&A) expenses in 2002, while the supply industry averaged about 26%. This expense item includes the cost of marketing, and thus the more specific clinical expertise required to sell new devices versus new hospital supplies. Variations in marketing costs may account for part of the difference between the two subsectors.

Net Income

To calculate net income (*i.e.*, profit or the “bottom line”), COGS, SG&A, R&D, and other expenses (including depreciation, amortization, interest, and taxes) are subtracted from total revenue. Net income is the amount that the business can reinvest in itself and, in the case of a for-profit company, may distribute to shareholders. Figure 7 shows a side-by-side comparison of average medical device and supply company spending for each expense, as a percent of total revenue, as well as average net income margins.

Figure 7: Comparison of Expenses: Device vs. Supply Companies, Year Ended 2002

Although device makers have a higher gross margin than supply companies, the two enjoy a similar profit levels.



Source: Company filings and Morgan Stanley.

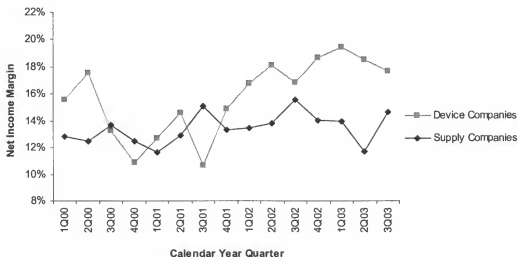
Note: Figures are medians. Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Device Company Margins Improve

Through 2002, device companies' net income margins improved from a nearly two-year low of 10%, peaking at 19%. Margin improvement is attributable to the introduction of new and more costly technologies such as cardiovascular and orthopedic devices. Supply company margins have remained consistent within historical trends. As discussed earlier in this report, certain supply companies with exposure to the pharmaceutical market have experienced dampened performance.

Figure 8: Median Net Income Margin, Quarterly Trends, 2000 – Present

Medical device company net income margins benefited from newly introduced technologies in 2002.



Source: Company filings.

Note: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

ACCESS TO CAPITAL

Large Medical Device and Supply Companies

Healthy Access to Public Equity and Debt Markets

Large medical device and supply companies generate significant operating cash flow.

Capital sources include the public equity and debt markets for the publicly traded companies. Large medical device manufacturers are able to generate enough cash from operations to fund a significant amount of their capital needs. The median earnings before interest and taxes (EBIT) for the largest medical device and supply companies approximated 26% of revenue in 2002. Because of their ability to generate cash flow, these large companies have less need to access the public debt and equity capital markets for capital. These large companies, however, may choose to draw on the capital markets to fund acquisitions or to refinance existing debt.

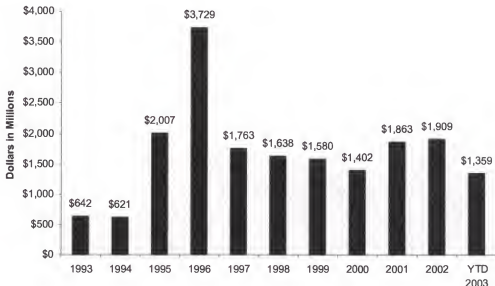
Health care is perceived as safe by investors.

David Lothson of UBS notes that “traditionally, healthcare has been among the more defensive investment sectors.” As a result of low investor confidence since the terrorist attacks of September 11, 2001 and the subsequent bear market, Lothson continues, “healthcare’s weighting has continued to remain above its historical average levels despite the poor performance of the sector’s largest component (pharmaceuticals) and the increasingly visible signs that the U.S. economy is recovering.” Poor performance within pharmaceuticals has driven investor interest towards other sub-sectors, including medical devices and hospital supply companies.

For example, since October of 2002, Baxter International has raised \$2.97 billion in debt and equity. In September, Baxter completed a public equity offering which raised approximately \$740 million. The company stated proceeds would be used to acquire certain assets from Alpha Therapeutics, among other uses.

According to Merrill Lynch, U.S. equity issuance for medical device and supply companies totaled \$1.9 billion in 2002 (for reference, the publicly-traded hospitals raised only \$62 million in equity). Figures 9 and 10 below indicate that the large medical device and supply companies have successfully raised capital in the public debt and equity markets.

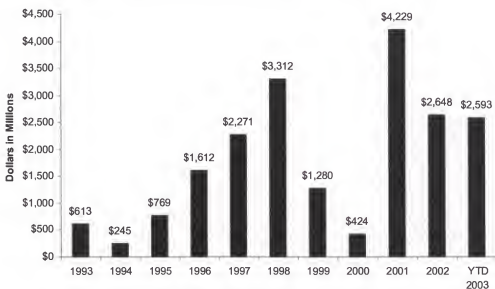
Figure 9: U.S. Medical Device Equity Issuance, 1993-2003 YTD



Source: Merrill Lynch and SDC as of October 25, 2003.

Notes: Excludes transactions less than \$25 million. Includes over allotment sold.

Figure 10: U.S. Medical Device Debt Issuance, 1993-2003 YTD



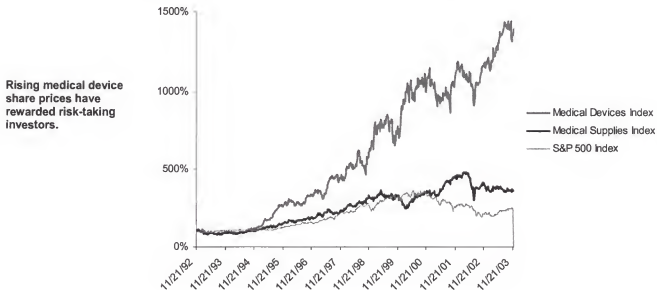
Source: Merrill Lynch and SDC as of October 25, 2003.

Notes: Excludes transactions less than \$25 million. Includes over allotment sold, convertible debt, convertible preferred stock, and non-convertible preferred stock.

Stock Market Performance

Stock market performance is a quantitative reflection of future expectations for risk and reward. Successful stock market performance can increase the ability of a company to raise capital by issuing stock. Over the past decade, the medical device and supply industry has outperformed the S&P 500 Index, with device manufacturers outperforming supply companies. This is shown in Figure 11 below.

Figure 11: Relative Stock Market Performance over Previous Decade



Source: Bloomberg through November 28, 2003.

Notes: Indices are market cap-weighted. Medical Devices Index includes Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Smith & Nephew, Stryker, and Zimmer. Medical Supplies Index includes Abbott Laboratories, Becton Dickinson, Baxter International, C.R. Bard, and Johnson & Johnson.

Through 2001 and much of 2002, medical supply stocks were better performers than medical device stocks due to the market's lower tolerance for risk. Medical device stock performance has improved largely due to new cardiovascular technologies (drug-eluting stents and biventricular pacing for congestive heart failure). Further, medical supply stock prices have been held back by drag created by their pharmaceutical business lines. This is shown in Figure 12.

Figure 12: Relative Stock Market Performance since 2001



Source: Bloomberg through November 28, 2003.

Notes: Indices are market cap-weighted. Medical Devices Index includes Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Smith & Nephew, Stryker, and Zimmer. Medical Supplies Index includes Abbott Laboratories, Becton Dickinson, Baxter International, C.R. Bard, and Johnson & Johnson.

Small Medical Device and Supply Companies

Investors provide less capital to the small medical device companies.

The small medical device companies are also much less likely to be publicly traded than large companies, and thus private equity investing is a critical source of capital.

Venture Capital Financing

Venture capital is an early-stage form of private equity investment that historically has played a vital role in funding and helping to develop emerging medical device companies. Venture capital funds focused on life sciences (biotechnology and medical devices) are among the few sources with both the longer time horizon required for developing companies, as well as a high risk tolerance. Small, unprofitable device companies rely on this patient capital in order to provide cash flow for continued operations. This is very different from the large profitable companies that generate positive cash flow to fund operations.

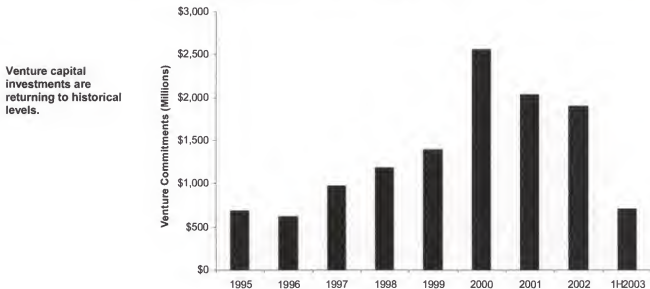
Venture capital has been vital in funding emerging medical device companies.

The PricewaterhouseCoopers/Thomson Venture Economics/National Venture Capital Association MoneyTree Survey notes:

Over the past five years, investing in the Life Sciences, [which includes both medical devices and biotechnology sectors], has continued at a comparatively steady pace relative to the venture capital market as a whole. The sector only partially benefited from the huge surge in venture capital investing that began in 1998, but it also did not suffer the steep declines of some technology industries as venture capital fell back to more normal levels by 2002.

Venture commitments in 2002 declined slightly from 2001 levels. Despite 54% growth in investments, to \$437 million, in 2Q2003 over the prior quarter, full year commitments may again show a slight decrease from 2002 levels.

Figure 13: Venture Capital Investment in Medical Device Firms, 1995-1H2003



Source: PricewaterhouseCoopers/Thomson Venture Economics/National Venture Capital Association MoneyTree™ Survey.

Fewer acquisitions reduce venture capital liquidity.

The venture capital investments market has slowed in recent years, mirroring the slowdown in mergers & acquisition activity, a key source of liquidity for venture investors. David Hetz of Cutlass Capital, a health care venture capital firm, notes that large acquirers historically felt pressure to acquire early stage companies on terms generally favoring the sellers because of aggressive competition from other corporate acquirers and the public markets. In recent years, however, fewer initial public offerings (IPOs) and discipline and patience on the part of the larger companies have led to fewer acquisitions. At the same time, deal structures have come to more closely align the interests of both parties and have allowed the acquired company and its investors to become partners in future product development and potentially commercialization.

Despite early signs of a recovery in the public markets, venture investors do not solely rely on access to the IPO market as a source of liquidity. This, in combination with the longer acquisition timelines, has led venture investors to become extremely disciplined in

Intellectual property protections are key to the value of a new technology.

their approach to assessing new investments in emerging companies. Venture investors take a conservative stance in deal structure and capital commitments realizing that the time required to reach liquidity may be protracted, requiring additional cash to fund operations.

Entrepreneurial companies face several barriers in attempting to secure venture investments. When evaluating potential investments, venture investors and large acquirers alike are principally concerned with the intellectual property protections in place for the new technology. Emerging technologies and new or improved techniques have the ability to significantly impact the market, and create substantial financial returns for their owners, but only if they cannot be easily “engineered around” or imitated. Available reimbursement and the visibility of regulatory hurdles are also key to investment decisions. Current reimbursement (or the potential for it) is critical to market acceptance of the new technology. Regulatory approval processes can significantly impact the time it will take a product to reach the market, which necessarily affects the capital required by the new company to fund operations in the interim.

Merger and Acquisition Activity

Following a slowdown, analysts expect M&A activity to increase.

In the last several years, merger and acquisition activity has slowed among the publicly traded companies. Contributing to the slowdown has been the increasing valuations of smaller life sciences companies over the last five years. Glenn Reicin of Morgan Stanley notes, however, “given the strong valuations of many of the companies in our coverage universe...a modest increase in expected M&A activity [is anticipated].” Larger medical device and supply companies are now finding the need to fill thin product pipelines or create growth to follow recently introduced technologies and are expected to begin acquiring smaller companies.

The lack of a thriving public market for small device stocks has historically made acquisitions an important liquidity opportunity for some investors. The continual innovation by startup device companies has resulted in new products and companies, which can be sold to larger companies that offer steady funding, better manufacturing, deeper distribution, and more experience in regulatory and payment processes. David Hetz of Cutlass Capital notes that venture capital investor dollars tend to follow those technologies developed by companies most likely to be acquired or eventually undergo public offerings. Most recently, these technologies have been within the orthopedics (specifically, spine) and cardiovascular arenas.

SUMMARY

- Overall, the medical device and supply industry enjoys robust financial health.
- Large medical device company spending on research and development remains strong—a sign of a healthy, sustained commitment to the industry's long-term success.
- Profit margins are strong among the large-cap medical supply and device companies.
- Large medical device and supply companies have successfully raised capital in the public debt and equity markets.
- Small medical device companies rely on venture capital investments to fund operations, and have experienced a decrease in investor willingness to commit capital.
- Merger and acquisition activity within the medical device industry is expected to increase as manufacturers seek to fill their product pipeline with new technology.

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